Alberta Health Services	**Botulism Antitoxin (Equine) Type A, B and E Biological Page**		
Section 7:	**Biological Product Information**		**Standard #: 07.200a**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
Approval Date:	July 18, 2014	**Revised:**	N/A

	Botulism Antitoxin Behring (Equine) Types A, B and E
Manufacturer	Novartis Vaccines and Diagnostics GmbH and Co. KG
Biological Classification	Antitoxin
Indications for Provincially Funded Vaccine	**Treatment of botulism for individuals 1 year of age and older** – suspected or confirmed (give immediately on suspicion of botulism - do not delay treatment waiting for lengthy clinical observations or confirmatory lab results). Botulism Antitoxin is not recommended for infants younger than one year of age. See #07.201 Baby Botulism Immune Globulin. • Eligibility will be determined though discussion amongst the treating physician, the zone Medical Officer of Health (MOH) and Alberta Health Chief Medical Officer of Health. o The zone MOH/MOH designate must notify the Office of the Chief Medical Officer of Health (OCMOH) by the fastest means possible of all cases in which botulism antitoxin is required. o OCMOH is available on a 24 hour basis by pager at 780-638-3630. o Once eligibility has been determined, OCMOH will authorize release of the product through either the Provincial Vaccine Depot or the Alberta Health Services (AHS) Calgary Vaccine Depot. It is not routinely stocked outside of these two sites. • Special authorization, access and transport procedures must be followed. This includes: o Ensuring the biological is packed and transported under strict cold chain management guidelines from the vaccine depot to the hospital unit. o Obtaining a signature for receipt of product from the treating physician. o Completion of Special Access Program Form C by the treating physician in conjunction with the zone MOH (a Special Access Program form is included with the product or can be found at http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf3_pasf3-eng.php) o Returning the completed Special Access Program Form C to the MOH/MOH designate. The zone MOH/MOH designate will review the Special Access Program Form C to ensure all fields are completed and then submit the completed form to AH. For further information about the disease and reporting requirements refer to the Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism.
Serology	Blood should be collected to identify the specific toxin before antitoxin is administered; however the administration of the antitoxin should not be withheld pending the test results (refer to the Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism).

	Botulism Antitoxin Behring (Equine) Types A, B and E
Schedule	**Treatment:** Infuse 250 mL slowly while observing for the circulatory effects. Follow with a continuous drip infusion of a further 250 mL. **Note:** • Depending on the degree of clinical improvement, a further 250 mL may be advisable 4 – 6 hours later.
Preferred Use	N/A
Dose	Refer to: Schedule section above and product monograph. **Note:** • Botulism antitoxin is supplied in vials containing 250 mL each. • This is a treatment product administered under the direction of a physician in an acute care setting.
Route	Slow IV infusion, preferably at body temperature, to ensure the quickest possible neutralization of toxin.
Contraindications/ Precautions	**Contraindications:** • None as this is a vital indication due to life-threatening condition. **Precautions:** • Patients may need to be assessed and tested for hypersensitivity to equine sera prior to administration of botulism antitoxin depending on the product used. Refer to product monograph or the Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism for further details. • Immune sera may be administered to patients with a history of allergic reactions to equine protein only in combination with a medication for the prevention of shock reactions.
Possible Reactions	The main possible reactions include hypersensitivity, anaphylaxis and serum sickness. • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information of possible reactions and recommendations for management of those reactions.
Pregnancy	• Pregnancy is not a contraindication for the use of Botulism Antitoxin Behring when clearly indicated.
Lactation	• Lactation is not a contraindication for the use of Botulism Antitoxin Behring when clearly indicated.
Composition	**Each 1 mL contains:** • Not more than 100 mg of equine protein with antitoxin against Cl. Botulinum • 750 I.U. Type A • 500 I.U. Type B • 50 I.U. Type E • Sodium chloride • Trace amounts of Phenol • Water for injection
Blood/Blood Products	Equine horse serum
Bovine/Porcine Products	None listed in ingredient list
Latex	None listed in ingredient list
Interchangeability	N/A

	Botulism Antitoxin Behring (Equine) Types A, B and E
Administration with Other Products	Must not be mixed with other medicinal products in a single container.
Appearance	Clear, colorless to pale yellow solution.
Storage	• Store at $+2^0$C to $+8^0$C. • Once the vial is opened, the preparation should be used immediately. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in original packaging when possible to protect from light.
Vaccine Code	BA
Antigen Code	BA
Licensed for	Botulism antitoxin is not approved for sale in Canada and is currently only available via Health Canada's Special Access Program (SAP).
Notes:	
Related Resources: • **AHS-Imm-07.200-R01 (June 30, 2017)** Botulism Antitoxin Information Sheet	

References:

1. Alberta Health, Acute Care and Population Health Division, Alberta Immunization Policy (2013, August 29). *Botulism Antitoxin Behring (Equine) Types A, B and E.*
2. Alberta Health. Botulism. In *Public Health Notifiable Disease Management Guidelines*. http://www.health.alberta.ca/professionals/notifiable-diseases-guide.html
3. American Academy of Pediatrics. (2012). *Red book: 2012 Report of the Committee on Infectious Diseases* (29th ed.) Elk Grove, IL: Author.
4. Novartis Vaccines and Diagnostics GmbH and Co. KG. (2006, September). Botulism Antitoxin Behring. *Product Information*.